

Section 2- 510(k) Summary

510(K) SUMMARY

JUL 24 2009

Imagine TC Skin Treatment System

510(k) Number K 083461

Applicant's Name: EndyMion Ltd
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North Industrial Park,
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Contact Person: Yoram Levy, Qsite
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Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
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Trade Name: *Imagine TC Skin Treatment System*

Classification: Name: Electrosurgical, cutting & coagulation device
& accessories

Product Code: GEI

Regulation No: 21 CFR 878.4400

Class: II

Panel: General & Plastic Surgery

Device Description:

The Imagine Skin Treatment System is a noninvasive, non-ablative device consisting of:

User interface

Programmable Logic controller (PLC)

RF power module

Thermoelectric cooling (TEC) module

Two treatment handpieces (small and large)

The interface allows the selection of treatment parameters by pressing on the treatment buttons;

LCD screen displays the current treatment settings. The PLC is a specially configured computer that provides the operational and safety function of the system. Handpieces incorporating:

Treatment handpieces with thermoelectric cooling (TEC) that maintains electrodes at ambient temperature.

The RF power module provides RF energy to the handpiece, producing a sinusoidal signal at a 1000 kHz frequency

Intended Use Statement:

The *Imagine TC Skin Treatment System* is a noninvasive device intended for use in Dermatologic and General Surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
Lumenis Aluma	K051214	Oct 24 2005
Alma Lasers Accent	K070004	Jan 18 2006
Thermage ThermaCool	K053365	Aug 30 2001
Syneron Polaris	K031671	Apr 07 2006

Performance Standards

Imagine TC Skin Treatment System complies with ANSI AAMI 60601-2-2 for safety of high frequency surgical equipment.

In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the following voluntary standards:

1. *EN 60601-1* (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
 - *IEC 60601-1-2* (Electromagnetic compatibility (EMC))

A detailed description appears in **Section 14**.

Summary of Clinical performance data

The safety and efficacy of radiofrequency devices emitting energy with a frequency of 1000 KHz with power of 10 to 100 W is well established in scientific research and clinical studies. Multiple studies with these and similar systems have shown safety in dermatologic therapy and the devices were cleared by the FDA for therapy of wrinkles and rhytides.

Due to the comprehensive animal and clinical study performed in scientific research and published in the literature, and since the power and frequency of the *Imagine TC Skin Treatment System* are well within the previously cleared values, EndyMion believes that animal and clinical studies are not required to determine the safety and efficacy of the device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EndyMion Ltd.
% Yoram Levy
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JUL 24 2009

Re: K083461

Trade/Device Name: Imagine TC Skin Treatment System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 6, 2009
Received: July 9, 2009

Dear Yoram Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

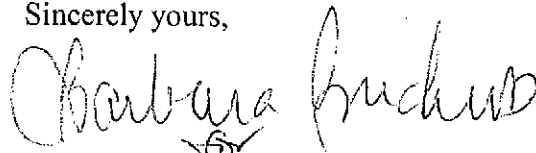
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Mark N. Melkerson", is written over a circular embossed seal of the Center for Devices and Radiological Health.

Mark N. Melkerson

Director

Division of Surgical, Orthopedic
and Restorative Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 083461

Device Name: *Imagine TC Skin Treatment System*

Indications for Use: The *Imagine TC Skin Treatment System* is a noninvasive device intended for use in Dermatologic and General Surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)

Division of General, Restorative and Neurological Devices

510(k) Number

Neil R. Doherty
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083461